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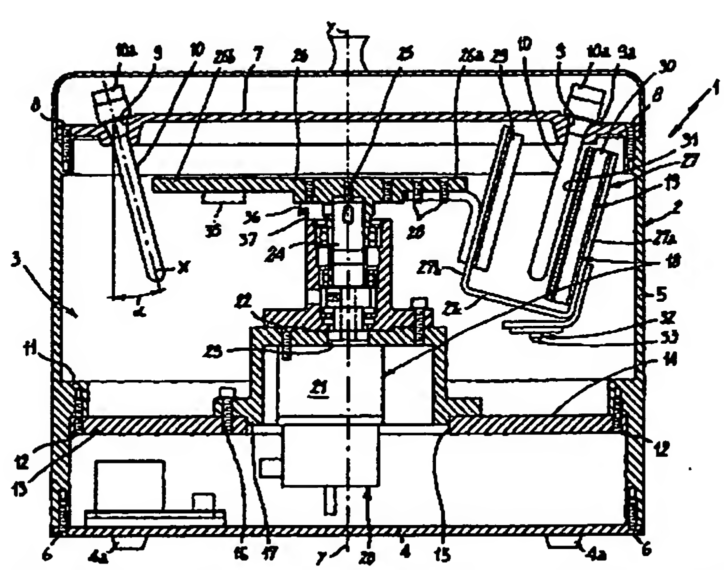
(54) Title: APPARATUS FOR TESTING BLOOD SAMPLES



(57) Abstract: An apparatus (1) for measuring the erythrosedimentation rate in blood samples comprises in its entirety a plurality of housing seats (9) each set to receive a test tube (10) containing a blood sample, a measuring element (19) set to measure the sedimentation level inside the test tube (10) and an electronic processing unit connected to the measuring element (19) to receive the data pertaining to the exam performed. The measuring element (19) comprises a CCD linear optical sensor (30) movable among the test tubes (10) to take a static reading of the sedimentation level of each test tube (10) under examination. The test tubes (10) are arranged according to a circumferential distribution line and the linear optical sensor (30) is moved along a circumferential trajectory concentric to the circumferential distribution line by means of a stepping motor (21).

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Description

Apparatus for Testing Blood Samples

Technical Field

The present invention relates to an apparatus for measuring erythrosedimentation rate in blood samples comprising the characteristics expressed in the preamble to claim 1.

In particular, the present invention is suitable for use in the field of medical diagnosis, for instance in hospitals and laboratories destined to conduct diagnostic exams.

More specifically, the invention is aimed at the measurement of the erythrosedimentation rate, commonly abbreviated in the sector with the acronym (VES), in blood samples.

Background Art

Normally, the measurement of the erythrosedimentation rate in a blood sample contained in an appropriate test tube is performed measuring the height of the plasma column overlying the red cells which, due to the difference in their density, have been deposited on the bottom of the test tube after a pre-set waiting period.

This measurement is normally performed with the aid of an automatic apparatus which in its entirety comprises a load-bearing structure whereon a plurality of housing seats are obtained, each destined to receive a test tube to be examined.

The apparatus further comprises a plurality of measuring elements, each associated to one of the housing seats, and movable simultaneously along the respective test tubes being examined to measure the sedimentation level present in each of them.

Each measuring element comprises an emitter diode and a respective receiver situated at opposite sides with respect to the test tube in such a way that the receiver

is able to be struck by a thin ray of infrared light sent by the emitter through the test tube itself.

An electronic processing unit manages the activation and movement of the measuring element to extrapolate, during the scanning operation, the data pertaining to the erythrosedimentation which took place in the various samples being examined.

More in particular, the execution of the analysis requires locating the test tubes, containing the samples to be examined, in the respective housing seats provided in the apparatus. Through micro-switch sensors or equivalent means associated to the individual housing seats, the electronic unit detects the insertion of the test tubes and, after a predetermined waiting period required for the red cells to separate from the plasma, commands the activation of the measuring elements. During the movement effected by each measuring element, the point-shaped beam of infrared light emitted by the respective diode scans the entire test tube. The passage of the infrared light beam through the test tube is allowed by the plasma, whereas it is prevented by the red cells. Consequently, the receiver is able to measure the level reached by the red cells settled in the test tube, due to the change in state brought about by the interception of the light ray by the sediment during the scanning operation, thereby signalling to the processing unit the level of sedimentation present inside the test tube being examined.

The measured value of the sedimentation level is then compared with already known reference parameters.

The known apparatuses described above are not free of some drawbacks.

In this regard it should be noted that, in order to assure a reliable measurement of the sedimentation level, the known apparatus is provided with diodes that emit respective very thin point-shaped infrared light beams. In this circumstance, a factor required for the reliability of the exam conducted not to be compromised is given by the co-planarity between each infrared light beam and the longitudinal axis of the respective test tube. Naturally, a perfect co-planarity between a point-shaped light beam and the axis of the test tube is quite difficult to achieve and maintain.

It should further be noted that this co-planarity must be guaranteed also during the motion of the measuring element along the longitudinal axis of the test tube. The apparatus therefore must comprise highly precise and reliable mechanical driving means.

It should also be considered that structural imperfections of the test tubes containing the blood samples can reflect or refract the light beams in an anomalous manner, altering the values of the analyses conducted. To avoid this problem, insofar as possible, it is necessary to employ special test tubes made of particular materials and presenting a high degree of structural precision. These problems are all the more accentuated in that, in order to reduce the possibility of errors in identifying the transition level between the sediment and the overlying plasma, highly thin test tubes are used, i.e. with a high length/diameter ratio, more prone to risks of lateral inflection.

Lastly, it should be noted that this apparatus does not allow to start scanning each blood sample under examination at different times. This limitation is brought about by the simultaneous motion of the measuring elements and by the long time intervals they need to scan the respective test tubes. In other words, in order to avoid risks of overlaps in the scanning times, it is necessary to wait for an exam to end in order to proceed with the following exam. Consequently, in order to optimise the scanning procedure and have the best possible performance on the part of the apparatus, it is necessary to occupy all housing seats before conducting an exam.

Disclosure of Invention

The main aim of the present invention is to overcome the drawbacks observed in the prior art, proposing an apparatus for measuring the erythrosedimentation rate in blood samples which ensures a reliable measurement of the sedimentation level in each blood sample analysed.

This and other aims which shall become more readily apparent in the course of the present description are substantially attained by an apparatus for measuring the

erythrosedimentation rate in blood samples, comprising the characteristics expressed in the characterising part of claim 1.

Further features and advantages shall become more readily apparent in the detailed description of a preferred, but not exclusive, embodiment of an apparatus for measuring the erythrosedimentation rate in blood samples according to the present invention. The description shall be provided below with reference to the accompanying drawings, provided purely by way of non-limiting indication.

Description of the Drawings

- Figure 1 shows an apparatus for measuring the erythrosedimentation rate in blood samples, sectioned according to trace I-I of Figure 2 with the sensor support arm mounted rotated by 90° with respect to that figure;
- Figure 2 is a partially interrupted plan view of the apparatus shown in Figure 1.

Description of the Illustrative Embodiment

With reference to the aforementioned figures, the number 1 indicates in its entirety an apparatus for measuring the erythrosedimentation rate in blood samples.

As shown in section in Figure 1, the apparatus 1 comprises a load-bearing structure 2, preferably made with cylindrical shape, defining a housing compartment 3.

More in particular, the housing compartment 3 is delimited by a bottom wall 4 of circular shape, and by a lateral wall 5 peripherally engaged to the bottom wall 4. The bottom wall 4 is externally fitted with appropriate support elements 4a destined to support the load-bearing structure 2 and the lateral wall 5 is rigidly engaged to the bottom wall 4 by means of first threaded elements 6.

On the side opposite to the bottom wall 4, a test-tube-holder element 7, substantially discoidal, is rigidly engaged by means of second threaded elements 8 to the lateral wall 5. More in detail, the test-tube-holder constitutes a closure element of the housing compartment 3.

On the test-tube-holder element 7 is further provided a plurality of housing seats 9 each of which is destined to receive a respective test-tube 10 containing a blood sample.

As Figure 2 shows, the housing seats 9 are situated in a peripheral area of the test-tube-holder element 7 according to a circumferential distribution line.

Advantageously, each housing seat 9 presents an axis of development substantially inclined with respect to an axis of symmetry of the load-bearing structure 2 in such a way as to maintain the respective test tube 10 oriented according to a predefined inclination angle α, preferably equal to 15°, measurable between the longitudinal axis "X" of the test-tube 10 and a vertical direction.

In detail, each housing seat 9 comprises a through hole obtained through the test-tube-holder element 7 and presents a bearing portion 9a substantially defined by a surface inclined with respect to a horizontal direction, according to which the test-tube-holder element 7 develops. The bearing portion 9a provides support for a bearing head 10a of the test tube itself.

Also with reference to Figure 1, from the lateral wall 5, and more specifically from the inner surface thereof, an annular support portion 11 projects towards the centre of the housing compartment 3. To the annular support portion 11 is rigidly engaged, by means of third threaded elements 12, at least an annular connecting element 13 defining a substantially horizontal support plane 14.

The annular connecting element 13 presents, in its central area, a through opening 15 in correspondence with which a support 17 is fastened by means of fourth threaded elements 16.

The support 17 is destined to sustain an operative structure 18, comprising in its essential parts at least a measuring element 19 provided to measure the sedimentation level inside each test tube 10 under examination, and driving means 20 to displace the measuring element 19 with respect to the housing seats 9 in such a way as to align it selectively with one of the test tubes 10 chosen on each occasion from those engaged in the respective seats 9.

More specifically, the driving means 20 comprise at least a motor 21, preferably of the stepping type, fastened inferiorly by means of fifth threaded elements 22 to the support 17, in such a way as to occupy the space defined by the through hole 15 of the annular connecting element 13.

From the motor 21, through a passage 23 obtained in the support 17, a drive shaft 24 extends vertically; in correspondence with an extremity of the drive shaft 24 is fastened, by means of sixth threaded elements 25, an arm 26 developing substantially perpendicular with respect to the drive shaft itself. Consequently, the arm 26 presents an axis of rotation "Y" substantially coinciding with the axis of symmetry of the load-bearing structure 2 and with the centre of the circumferential distribution line of the test tubes 10.

The arm 26 presents a first extremity 26a provided to bear the measuring element 19 and a second extremity 26b which counterbalances the load bearing down on the first extremity 26a.

In correspondence with the first extremity 26a of the arm 26, a support 27, shaped substantially as a "U", is rigidly engaged to the arm itself, by means of seventh threaded elements 28.

The support 27 presents at least a first lateral element 27a and at least a second lateral element 27b joined to the first lateral element 27a by means of at least a connecting portion 27c.

As shown in Figure 1, the lateral elements 27a, 27b of the support 27 are directed substantially parallel with respect to the longitudinal axis of the test tube, i.e. according to a direction inclined by 15° with respect to a vertical direction.

It is important to note that the measuring element 19 is fastened onto the first lateral element 27a in such a way as to face the test tube 10 under examination, by way of indication at a distance ranging between 3 mm and 5 mm from the outer surface thereof, whilst on the second lateral element 27b may be fastened a light emitter 29 facing the measuring element 19. The test tube 10 under examination is therefore interposed between the light emitter 29 and the measuring element 19.

The measuring element 19 comprises at least a linear optical sensor 30 of the type commonly identified with the acronym "CCD" (charge-coupled device), presenting at least a row of photosensitive elements set consecutively side by side with respect to one another to define a linear photosensitive portion 31 which, in addition to facing the test tube 10, extends along the development thereof. This linear optical sensor 30 is able to detect differences in luminosity along the development of the test tube 10, allowing the execution of a static measurement of the sedimentation level present inside the test tube itself.

The photosensitive portion 31 may comprise two or more rows of photosensitive elements, set mutually side by side in such a way that the linear photosensitive portion 31 develops according to a substantially rectangular plane.

For further information, the reader is referred to US Patent 5,920,346 wherefrom the constructive and operating principles of CCD linear optical sensors can be obtained.

By way of indication, a type of known linear CCD usable in the subject apparatus is produced and/or marketed by the company Thomson-CSF under the designation CCD-BAR 12000 pixels.

By means of the motor 21, both the linear optical sensor 30 and the light emitter 29 are movable according to a circumferential trajectory concentric to the circumferential distribution line of the test tubes 10 to determine the alignment of the linear optical sensor 30 with respect to the test tube under examination. The circumferential trajectory described by the light emitter 29 is situated internally with respect to the circumferential distribution line, whilst the circumferential trajectory described by the linear optical sensor 30 is external to the circumferential distribution line.

It should in any case be noted that, for the purposes of selectively positioning the linear optical sensor 30 with respect to the test tubes 10, it is also possible to provide for the test-tube-holder element 7 to be able to rotate about the axis of symmetry of the load-bearing structure 2 by means of appropriate actuating means,

in such a way as to bring each test tube 10 under examination in correspondence with the linear optical sensor itself.

An electronic processing unit (not shown in the drawings) is further provided to regulate and synchronise the various components comprising the apparatus 1. The electronic processing unit is connected with the linear optical sensor 30 to receive therefrom the data relating to the measurements performed.

Specifically, the electronic processing unit can be located directly on the bearing plane 14 of the annular connecting element 13, or it can be provided directly on an appropriate board which is mounted on the annular connecting element 13.

For the transmission of the data from the linear optical sensor 30 to the electronic processing unit, the apparatus 1 provides for the presence of at least an optical interface 32. Such optical interface 32 comprises at least an emitting optical element 33 fastened to the connecting portion 27c of the support 27 and at least a receiver 33a situated on the board of the electronic processing unit. Preferably, on the board of the electronic processing unit are positioned three receivers, mutually distanced according a 120° angle about the axis of rotation "Y" to ensure data communication between the linear optical sensor 30 and the electronic processing unit.

The use of the optical interface 32 advantageously allows to transmit the data without requiring the aid of electrical conductors connecting the linear optical sensor 30 and the electronic processing unit, with the consequent need to adopt complex technical solutions to allow the arm 26 to rotate freely.

For the purposes of the electrical power supply to the linear optical sensor 30, to the light emitter 29 and to the optical emission element 33, it is advantageously possible to provide, for instance on the arm 26, at least an electrical accumulator 35 whereto are operatively combined a movable electrical contact 36 and a fixed electrical contact 37 respectively associated to the arm 26 and to the support 17 or other fixed part of the apparatus 1. The movable contact 36 and the fixed contact 37 are able to come respectively in contact to allow the supply of electrical power to the

accumulator 35, with its consequent charge, every time the arm 26 is located in a predetermined rest position upon command from the aforementioned electronic processing unit.

The apparatus further comprises a programming interface 34 to allow a user to select, for each test tube 10 present in the test-tube-holder element 7, the type of exam to be performed. To the programming interface 34 can further be associated a printing unit (not shown) whereby the results of the exams performed can be printed on hardcopy supports.

The operation of the apparatus for the measurement of the erythrosedimentation rate in blood samples, described above in a mainly structural sense, is as follows.

One or more test tubes 10 containing the blood samples to be examined are positioned each in one of the housing seats 9 of the test-tube-holder element 7.

By means of known signalling systems, the electronic processing unit receives a signal pertaining to the occupation of the housing seats 9 whereinto the test tubes 10 have been inserted.

Simultaneously with the insertion of the test tubes 10, the activation of the optical sensor 30 and of the motor 21 is commanded to perform an initial scan on each test tube 10, aimed at measuring the column of blood introduced in the test tube itself.

Through the programming interface 34, the user can select the type of exam to be conducted for each of the blood samples contained in the test tubes 10, and command the start of the process for measuring the sedimentation level in each blood sample.

Once the measuring process has been started, the apparatus 1 proceeds to measure the sedimentation level after the pre-set waiting time selected according to the type of exam to be performed. Upon expiration of the waiting period, the electronic processing unit activates the motor 21. The shaft 24, the arm 26 and consequently also the linear optical sensor 30 together with the light emitter 29,

rotate about the axis of rotation "Y", clockwise or counter-clockwise depending on the lesser angle which the linear optical sensor 30 has to travel to align with the test tube 10 to be measured.

Once the linear optical sensor 30 and the light emitter 29 are aligned with respect to the test tube 10, the light emitter 29 illuminates the test tube 10 on the opposite side with respect to the linear optical sensor 30. Consequently, the photosensitive portion 31 detects a shadow area projected by the column of red cells which prevent light from passing through the test tube 10, and a lighted area relating to the plasma column which allows light to pass through.

To assure an optimal reading definition, to the linear optical sensor 30 can advantageously be associated an optical system with one or more lenses to focus the image of the blood sample on the photosensitive portion 31.

Through the optical interface 32, the optical sensor 30 sends to the electronic unit the data pertaining to the dimensions of the shadow area and of the lighted area on the linear photosensitive portion 31, directly correlated to the sedimentation level reached in the test tube. The electronic processing unit, suitably programmed, is therefore able to provide the erythrosedimentation values resulting from the exam performed, after processing the data received from the sensor 30.

The present invention attains important advantages.

First of all, the subject apparatus allows to perform correct and reliable blood tests even in the presence of structural imperfections of the test tubes employed, since the constructive and functional conception of the linear optical sensor allows simultaneously to detect the light the passes through along the entire development of the test tube under examination.

It should further be noted that such linear optical sensor allows precisely to measure the level of sedimentation in the test tube under examination in conditions of misalignment between the longitudinal axis of the test tube and the photosensitive portion of the linear optical sensor. This situation has allowed the development and realisation of an apparatus that is faster and more versatile than those of the prior art,

thanks to the use of a single sensor able to move among the various test tubes to measure directly in each of them the respective erythrosedimentation level.

It should also be considered that the constructive and functional principles of the CCD optical sensors are such that the latter need not be moved along the development of the test tube during the measuring phase, but rather it advantageously performs this measurement instantly along the entire development of the test tube under examination. Consequently, the subject apparatus does not need complex mechanical driving means, employed in known apparatuses to make the emitter diodes slide in a precise manner along the longitudinal axes of the respective test tubes.

Moreover, also with reference to the instantaneous reading which can be taken with the linear optical sensor, it is possible to take a reading from each test tube under examination even with the sensor in motion, i.e. without necessarily arresting the rotation of the arm 26 when the linear optical sensor is aligned with the test tube itself. The electronic processing unit, through the stepping motor and/or encoders or equivalent means known in themselves, is able to know at each instant the angular position assumed by the arm and, therefore, correctly to attribute to each test tube the data measured by the sensor after the reading.

It should further be noted that the reading speed of the CCD optical sensor, nearly instantaneous, allows to conduct on each test tube, between the initial and the final reading, a series of intermediate readings separated by very short time intervals, even in the order of a few tenths of a second. Consequently it is possible to define, for each blood sample under examination, a graph which shows in detail the profile of the sedimentation over time instead of limiting itself, as is the case in the state of the art, to measure a single value corresponding to the final reading conducted after a pre-set time.

The apparatus according to the invention is also able simultaneously to perform the examination of several blood samples, handling them independently from each other. More in particular, while reading a test tube, it is possible to insert one or

more test tubes destined to be examined. This condition is advantageous with respect to the prior art where the reading is taken simultaneously on all loaded samples forcing the user to wait for the end of the examination before inserting the new samples to be examined.

It should also be considered that, thanks to the properties of the CCD linear optical sensor, it is possible to use test tubes with mutually different dimensions and shapes, without being limited to the use of test tubes with rigorously pre-set shape and dimensions, as is the case in the prior art.

Claims

1. Apparatus for measuring the erythrosedimentation rate in blood samples comprising:

- at least a housing seat (9) in correspondence with which at least a test tube (10) containing a blood sample can be positioned;
- at least a measuring element (19) provided to measure the sedimentation level inside said test tube (10) after a predetermined waiting interval;
- at least an electronic processing unit connected to the measuring element (19) to receive data pertaining to the sedimentation level measured in said test tube (10);

characterised in that said measuring element (19) comprises at least a linear optical sensor (30) presenting at least a row of photosensitive elements set consecutively side by side with respect to one another to define a photosensitive portion (31), said photosensitive portion (31) facing the test tube (10) and developing along the extension of the test tube itself.

2. Apparatus according to claim 1, comprising:

- a plurality of housing seats (9) each destined to receive a test tube (10) containing a blood sample;
- driving means (20) to move the measuring element (19) with respect to the housing seats (9) and align said measuring element (19) selectively to one of the seats themselves.

3. Apparatus according to claim 2, wherein said housing seats (9) are arranged according to a circumferential distribution line and said measuring element (19) is movable according to a circumferential trajectory concentric to the circumferential distribution line.

4. Apparatus according to claim 3, wherein said driving means (20) are

mechanically connected to said measuring element (19) to move the latter along said circumferential trajectory.

5. Apparatus according to claim 2, wherein said driving means (20) comprise:
- at least a motor (21);
- at least a drive shaft (24) operatively associated to said motor (21);
- an arm (26) extending transversely from the motor shaft (24) and bearing said measuring element (19).

6. Apparatus according to claim 5, wherein said motor (21) is a stepping motor.

7. Apparatus according to claim 5, wherein said arm (26) presents an axis of rotation ("Y") coinciding with the centre of said circumferential distribution line.

8. Apparatus according to claim 1, further comprising a light emitter (29) facing said photosensitive portion (31) of said linear optical sensor (30), said light emitter (29) illuminating at least partially the photosensitive portion (31).

9. Apparatus according to claim 8, wherein said light emitter (29) is rigidly engaged with respect to said linear optical sensor (30), said test tube (10) under examination being interposed between said linear optical sensor (30) and said light emitter (29).

10. Apparatus according to claim 5, further comprising at least a support (27) shaped substantially as a "U" borne by the arm (26), said support (27) comprising:
- at least a first lateral element (27a) in correspondence with which said linear optical sensor (30) is fastened;
- at least a second lateral element (27b) positioned parallel with respect to the first lateral element (27a).

11. Apparatus according to claim 1, wherein each housing seat (9) is set to hold the test tube (10) according to an inclined orientation with respect to a vertical direction.

12. Apparatus according to claim 1, further comprising an optical interface (32) set to transmit the data measured by the linear optical sensor (30) to said electronic processing unit.

13. Apparatus according to claim 1, further comprising:
- at least an electrical accumulator (35) borne by said arm (26) to supply power to said linear optical sensor (30);
- at least a movable contact (36) connected to said arm (26);
- at least a fixed contact (37) connected to a fixed part of said apparatus;

said movable contact (36) and fixed contact (37) being set to engage mutually to recharge said electrical accumulator (35) when the arm (26) is placed in a rest position on command from said electronic processing unit.

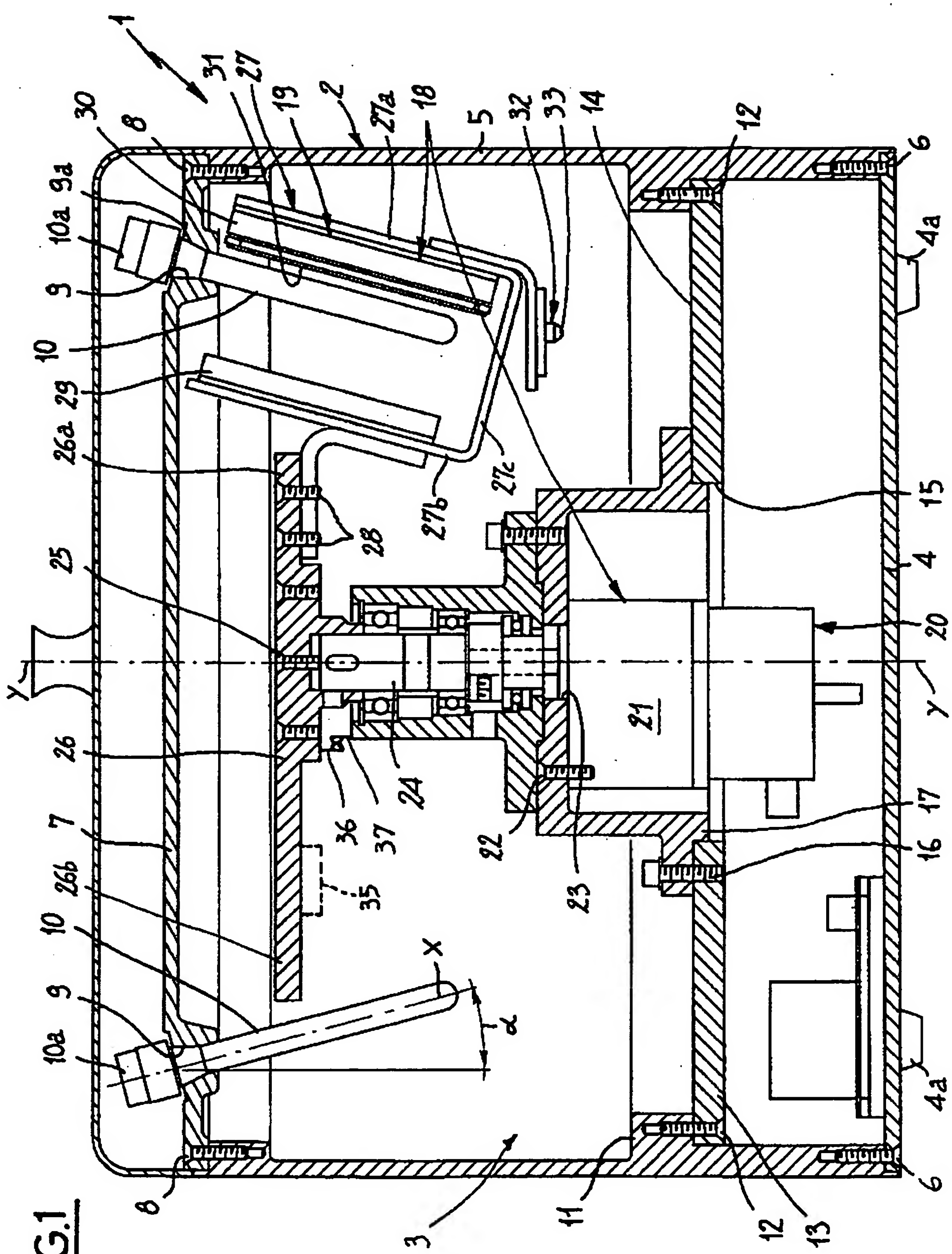
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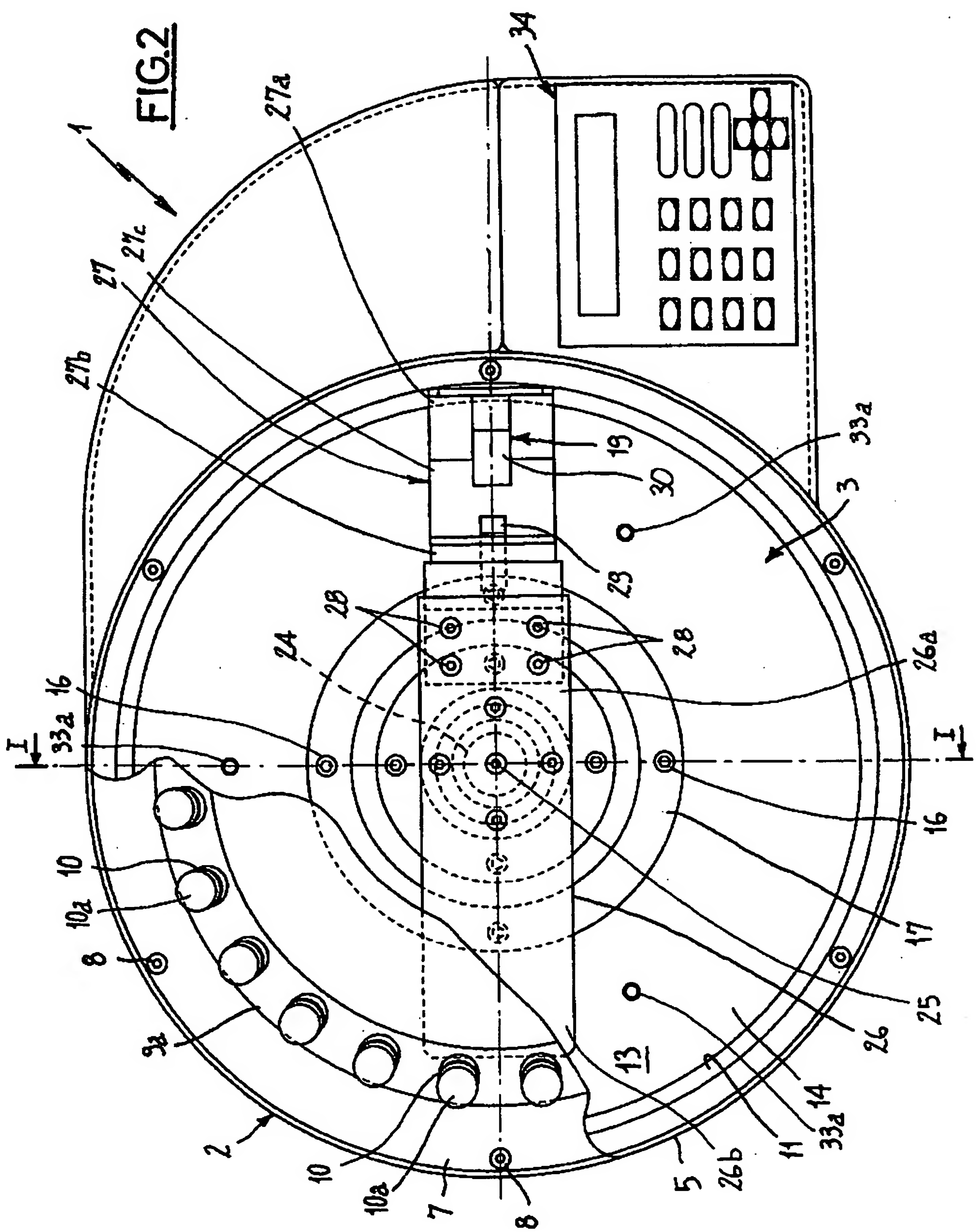
FIG.1

FIG.2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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01N15/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 342 730 A (SCHOUTEN THEODORUS) 23 November 1989 (1989-11-23) claim 24; figure 4	1-7,12
X	US 5 003 488 A (HARDY FRANCOIS) 26 March 1991 (1991-03-26) claim 5; figure 4	1
X	US 4 710 874 A (CINQUALBRE PAUL-HENRI) 1 December 1987 (1987-12-01) column 1, line 59 -column 2, line 2	1
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search	Date of mailing of the international search report
25 November 1999	02/12/1999

Name and mailing address of the ISA	Authorized officer
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1

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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